

Claim 69, line 1, after "said" please insert --probe--.

Claim 70, line 1, after "said" please insert --probe--.

REMARKS

Applicants have proposed amending claims 42-49, 52-59, and 62-70 to recite previously unrecited subject matter. Specifically, Applicants have amended the claims to recite "A method of detecting HIV-2 retrovirus nucleic acid," not just "HIV-2 retrovirus RNA." This amendment is supported by Examples II and III of the specification, which involve hybridization of probes to, not just HIV-2 RNA, but also HIV-2 DNA extracted from infected cells. Specification at page 35, lines 31-33; page 36, lines 22-23.

Applicants have also amended claims 42, 52, and 62 to recite that the probe nucleic acid is selected from the group consisting of nucleic acid that does not hybridize to nucleotides 5290-9130 of HIV-1 under non-stringent conditions and nucleic acid that does not hybridize to nucleotides 2170-2240 of HIV-1 under non-stringent conditions. The specification supports these amendments at the sentence bridging pages 46 and 47. Upon entry of this Amendment, claims 42-49, 52-59, and 62-71 will be pending in this application.

Priority rights under 35 U.S.C. §§ 119 and 120 (Item 2)

The Examiner contends that the instantly claimed invention does not receive support in either parent application Serial No. 06/835,228, filed March 3, 1986, or foreign priority application FR 86.04215, filed March 24, 1986. After making this statement, the Examiner directs Applicants to application Serial No. 07/003,764, filed January 16, 1987. July 9, 1996, Office Action at page 1, lines 13-16. It appears from

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the statement that the Examiner views this application as the first priority application containing the nucleotide sequences of HIV-2 LTR, *gag*, and *env* regions.

Applicants respectfully disagree with this characterization. Application Serial No. 06/916,080, filed October 6, 1986, disclosed the nucleotide sequence of U3/R region of HIV-2 at page 13. This sequence corresponds to the sequence of Figure 6 in the present application. Thus, this sequence was disclosed by October 6, 1986.

A copy of this application, including its Declaration, and the PTO date-stamped postcard evidencing its receipt, is enclosed.

**Rejection of claims 42-49, 52-59, and 62-71
under 35 U.S.C. § 112, first paragraph (Item 3)**

The Examiner rejected claims 42-49, 52-59, and 62-71 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled by the specification on several grounds. Applicants respectfully traverse this rejection.

Specifically, the Examiner contends that the specification must teach the corresponding genomic locations, precise nucleotide sequences, lengths, and specificity of the probes used in the claimed method. Paper No. 9 at sentence bridging pages 2 and 3.

Applicants respectfully disagree with this assertion. Preliminarily, Applicants note that all the pending claims, except for claims 42, 52, 62-63, and 70-71 cite the corresponding genomic locations, nucleotide sequences, lengths, and specificity of the probes of the claimed method.

Nonetheless, Applicants respectfully contend that they need not teach the corresponding genomic locations, nucleotide sequences, lengths, and specificity of all probes that would function in the claimed method. Applicants successfully used various

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HIV-2 probes to detect the presence of HIV-2 nucleic acids. For example, Applicants used the insertion clone F1.1 in a dot blot, and Applicants used the insertion clone E2.1 in both a Southern blot and a dot blot. Specification at page 32, line 5, through page 33, line 11; page 40, first full paragraph. Furthermore, Applicants used eleven HIV-2 fragments in mutual hybridization experiments with HIV-1 fragments and found little hybridization, even under very low stringency conditions. Specification at page 26, line 25, through page 27, line 15. Thus, one of ordinary skill in the art would have been able to produce and use other HIV-2 nucleic acid probes to detect HIV-2 retroviral nucleic acids based upon Applicants' disclosure.

The Examiner also contends that Applicants' claims should recite the hybridization and washing conditions. As Applicants discussed in their previous Amendment, the current claims do recite the hybridization and washing conditions, i.e., stringent or non-stringent. Applicants respectfully submit that these terms have a well-known meaning in the art. Furthermore, Applicants have defined these terms in the specification at page 17, lines 15-35.

Finally, the Examiner contends that one skilled in the art could not generate the cDNA corresponding to the full-length viral genome, *gag*, *pol*, or *env* from the teachings of the specification. Applicants respectfully disagree. Indeed, as discussed in the specification, Applicants themselves generated a cDNA corresponding to the full-length viral genome of HIV-2. Specification at page 38, lines 8-12. Furthermore, Applicants sequenced the *gag*, *pol*, and *env* regions of this complete HIV-2 cDNA. Specification at page 55, lines 9-12.

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For the above reasons, one of ordinary skilled in the art would have been able to practice the claimed invention without undue experimentations. Thus, Applicants respectfully request withdrawal of this rejection.

**Rejection of claims 42, 52, and 62
under 35 U.S.C. § 102(a) (Item 5)**

The Examiner rejected claims 42, 52, and 62 under 35 U.S.C. § 102(a) as allegedly being anticipated by Clavel et al. (1986, Science). Specifically, the Examiner contends that this Clavel et al. reference discloses HIV-1 probes that cross-hybridized with HIV-2 RNA. Paper No. 5 at page 7, lines 6-9. Furthermore, the Examiner contends that Applicants' invention is not enabled by, and is not entitled to the benefit of, the earlier applications. Paper No. 9 at sentence bridging pages 5 and 6.

Applicants respectfully traverse this rejection. Preliminarily, Applicants note that claim 62 recites "stringent conditions" (emphasis added). In contrast, the Clavel et al. probes referred to by the Examiner only hybridize to HIV-2 RNA under non-stringent conditions. Clavel et al. (1986, Science) at Figure 5, lines 9-14. Therefore, Clavel et al. (1986, Science) cannot anticipate claim 62.

Furthermore, the Examiner contends that Clavel et al. (1986, Science) teach HIV-1 probes that hybridize weakly with HIV-2 RNA under non-stringent conditions. Paper No. 5 at page 7, lines 6-9. Applicants respectfully traverse this rejection. Nonetheless, solely to expedite allowance of the pending claims, and not in acquiescence to this rejection, Applicants have amended claims 42, 52, and 62 to recite that the probe nucleic acid is selected from the group consisting of nucleic acid that does not hybridize to nucleotides 5290-9130 of HIV-1 under non-stringent conditions and nucleic acid that does not hybridize to nucleotides 2170-2240 of HIV-1 under non-

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stringent conditions. These amendments are supported at the sentence bridging pages 46 and 47. Accordingly, Applicants respectfully request withdrawal of this rejection.

**Rejection of claims 42-44, 52-54, and
62-64 under 35 U.S.C. § 102(a) (Item 6)**

The Examiner rejected claims 42-44, 52-54 and 62-64 under 35 U.S.C. § 102(a) as allegedly being anticipated by Clavel et al. (1986, Nature). Specifically, the Examiner contends that this reference describes molecular cloning of the complete 9.5 kb genome of HIV-2 and the E2 cDNA probe recited in claims 44 and 54. Paper No. 5 at page 7, lines 16-25. Furthermore, the Examiner again contends that Applicants' invention is not enabled by, and is not entitled to the benefit of, the earlier applications. Paper No. 9 at page 6, lines 11-12.

Applicants enclose a copy of application Serial No. 06/933,184, filed November 21, 1986, which, as discussed above, contains hybridization data, and the PTO mailroom date-stamped postcard evidencing receipt of this application. M.P.E.P. § 503. The Clavel et al. (1986, Nature) reference was published on December 25, 1986, after Applicants filed application Serial No. 06/933,184. Therefore, Clavel et al. cannot be used as a reference against these claims, and Applicants respectfully request withdrawal of this rejection.

**Provisional Rejection of claims 42-49, 52-59,
and 62-71 under the judicially created doctrine
of obviousness-type double patenting (Item 7)**

The Examiner provisionally rejected claims 42-49, 52-59, and 62-71 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 42-46 and 48-50 of copending application Serial No. 08/392,613. Specifically, the Examiner contends that Applicants have not provided

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evidence of the December 11, 1992, Office Action in predecessor application Serial No. 07/792,524, filed November 18, 1991, in which the Examiner required restriction between the presently claimed invention and the invention of application Serial No. 08/392,613. Paper No. 9 at page 6, lines 20-24.

Applicants submit herewith a copy of the December 11, 1992, Office Action in predecessor application Serial No. 07/792,524. Accordingly, Applicants have provided the evidence requested by the Examiner, and Applicants respectfully request withdrawal of this provisional rejection.

Provisional rejection of claims 42, 49, 52, 59, 62, and 69 under the judicially created doctrine of obviousness-type double patenting (Item 8)

The Examiner provisionally rejected claims 42, 49, 52, 59, 62, and 69 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 83 of copending application Serial No. 08/250,103. Applicants note that this is a provisional rejection; the reference is a copending application, not an issued patent. Therefore, Applicants respectfully request that this rejection be held in abeyance until claims are allowed in either this application or the cited application.

Rejection of claims 42-49 and 62-69 under 35 U.S.C. § 112, second paragraph (Item 9)

The Examiner rejected claims 42-49 and 62-69 under 35 U.S.C. § 112, second paragraph, as allegedly being multiplicative. Specifically, the Examiner contends that claims 42-49 and 62-69 are merely duplicate of each other. Paper No. 9 at page 7, lines 10-11.

Applicants respectfully traverse this rejection. Claims 42-49 recite "non-stringent conditions," while claims 62-69 recite "stringent conditions." (emphasis added). Thus,

these claims are not multiplicative, and Applicants respectfully request withdrawal of this rejection.


Applicants respectfully submit that entry of this Amendment will not necessitate a further search and will put this application in condition for allowance. Alternatively, Applicants submit that entry of this Amendment will reduce and clarify the issues for appeal. Accordingly, Applicants respectfully request entry of this Amendment and timely issuance of a Notice of Allowance.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136, not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Date: January 9, 1997

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